General

Guideline Title

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 55 p. (Technology appraisal guidance; no. 279).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people:

- Who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and
- In whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.

Clinical Algorithm(s)

A National Institute for Health and Care Excellence (NICE) pathway for osteoporosis is available on the NICE Web site .

Scope

Disease/Condition(s)

Osteoporotic vertebral compression fractures

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Neurological Surgery

Neurology

Orthopedic Surgery

Rheumatology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To determine the clinical effectiveness and cost-effectiveness of percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures

Target Population

People with osteoporotic vertebral compression fractures

Interventions and Practices Considered

1. Percutaneous vertebroplasty
2. Percutaneous balloon kyphoplasty

Major Outcomes Considered

- Clinical effectiveness
    - Health-related quality of life
    - Back-specific functional status/mobility
    - Pain/analgesic use
    - Vertebral body height and angular deformity

- Progression of treated fracture
- Incidence of new vertebral fractures
- All-cause mortality
- Symptomatic and asymptomatic leakage of cement (e.g., into adjacent intervertebral discs)
- Periprocedural balloon rupture
- Post-operative complications (including infection)
- Other adverse events
- Resource utilisation

- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), the University of Sheffield (see the "Availability of Companion Documents" field).

Methods for Reviewing Clinical Effectiveness and Safety

A systematic review was undertaken according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Identification of Studies

Extensive searches were undertaken with the aim of comprehensive retrieval of studies of clinical and cost-effectiveness relating to the research question.

The search strategy comprised the following main elements:

- Searching of electronic databases listed below
- Scrutiny of bibliographies of retrieved papers and previous systematic reviews
- Contact with experts in the field.

Electronic Searches

The searches aimed to systematically identify all literature relating to the clinical and cost-effectiveness of percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatments for osteoporotic compression fractures in men and women of all ages. A comprehensive database of relevant published and unpublished articles was constructed using Reference Manager© software.

Sources Searched

The following electronic databases were searched from inception: Medline (Ovid); Medline in Process; CINAHL; EMBASE; EconLit; the Cochrane Library including the Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register (CCTR), Database of Abstracts of Reviews of Effects (DARE), National Health Service Economic Evaluation Database (NHS EED), and Health Technology Assessment Database (HTA) databases; Science Citation Index (SCI). The searches were conducted in November 2011.

Search Terms

The search strategy was developed in collaboration with the information specialist. Search terms included 'vertebroplasty', 'kyphoplasty', and a broad variety of related clinical terms (e.g., 'bone void fill', 'vertebral augmentation') in order to obtain a wide scope. No bibliographic filters were used. Vocabulary around vertebroplasty/kyphoplasty is limited, therefore few synonyms where available. The searches were simple with an emphasis on sensitivity, utilising both keywords and MeSH/thesaurus terms where available. The Medline search strategy is provided in Appendix 1 of the Assessment Report. Search strategies for the other databases are available on request.

Search Restrictions

Searches were not restricted by language, publication date, or publication type (with exception of removing letters, news, editorials etc.). Furthermore, they were not restricted by study design, because studies which did not meet the inclusion criteria for the review of clinical effectiveness might provide relevant information relating to adverse events or be important in identifying further relevant papers and current research.

Scrutiny of Bibliographies of Retrieved Papers and Previous Systematic Reviews

The bibliographies of retrieved papers and the manuscripts were scrutinised to identify relevant evidence.

Contact with Experts in the Field

The clinical expert in the field was also consulted on whether the search had missed any relevant studies. The expert believed that all the relevant randomised controlled trials (RCTs) had been successfully identified.

Inclusion and Exclusion Criteria

Inclusion Criteria

Population

The population comprised people of any age and either gender with painful osteoporotic vertebral compression fractures. Studies which also included participants with non-osteoporotic vertebral fractures of other aetiologies (e.g., fractures associated with trauma, myeloma, or metastatic cancer) were included if data relating to participants with osteoporotic fractures could be extracted separately, or if the proportion of participants with non-osteoporotic fractures was extremely small.

Intervention(s)

Percutaneous vertebroplasty (PVP); percutaneous balloon kyphoplasty (BKP) with or without vertebral body stenting.

Comparator(s)

The interventions themselves, non-invasive management, operative placebo with local anaesthesia (OPLA), or no treatment.

Outcomes

See the "Major Outcomes Considered" field for the primary and secondary outcomes of interest for this appraisal.

Only studies which reported data relating to at least one of the primary outcomes in relation to the population of interest were eligible for inclusion in the review of clinical effectiveness. This criterion was relaxed for consideration of adverse events, to allow the inclusion of studies which reported data relating to any of the secondary outcomes in the population of interest. However, adverse event data were included only if they related to patients with osteoporotic vertebral compression fracture (VCFs) because of the possibility that patients with fractures of different aetiology (e.g., malignancy) might be susceptible to more, or different, adverse events.

To facilitate comparison, outcomes measured at or before three weeks are grouped together as short-term outcomes, those measured between one and six months as medium-term outcomes, and those measured at 12 months or later as long-term outcomes.

Study Design

According to the accepted hierarchy of evidence, the review of clinical effectiveness was limited to RCTs, as they provide the most authoritative form of evidence. It was planned that non-randomised studies would be considered if insufficient data were available from RCTs, but this was not necessary.

In reviews of interventions for which beneficial effects are uncertain or contentious, with some possibility of harm, an accompanying review of

adverse events (AEs) can be of substantial importance when deciding whether to use the intervention. It is widely recognised that RCTs do not form a good source of evidence for adverse events: they are generally not powered to reliably detect rare adverse effects, nor is their follow-up period long enough to permit the detection of adverse effects widely separated in time from the original intervention. In addition, their populations are often not wholly typical of the target population: they may be younger and have fewer comorbidities than the general population of patients with the condition of interest. Moreover, RCTs do not always measure all potential side-effects. Hence, it was decided to review the literature on AEs in PVP and BKP to provide additional support for clinical decision making. AEs were addressed using two broad research questions, namely, "what AEs are associated with PVP or BKP in the treatment of osteoporotic VCFs?" and "what is the approximate incidence of AEs associated with PVP or BKP in the treatment of osteoporotic VCFs?" Although this broad approach risked an overload of heterogeneous data which could not be easily pooled, it had a two-fold advantage: first, it could identify new or previously unrecognised complications, and second, it could provide a more comprehensive overview of potential complications.

Two types of evidence were included in the review of safety:

- Large observational studies (≥200 patients), which would allow exploration of the range and incidence of adverse events associated with PVP and BKP. The decision to include only large observational studies was based on a desire to exclude small case series which might display particularly high adverse event rates associated with limited experience of the relevant techniques on the part of the clinician or institution. The decision to set the threshold for inclusion at 200 patients was taken *a priori*.
- Individual case reports were used to supplement the RCTs and large observational studies to provide as full a picture as possible of the range of adverse events associated with PVP and BKP. They were therefore used as a source of evidence relating only to adverse events which were not reported in the RCTs or large observational studies. By their nature, individual case reports cannot provide any indication of the incidence of such adverse events.

As with the review of clinical effectiveness, studies which included participants with non-osteoporotic vertebral fractures of other aetiologies (e.g., fractures associated with trauma, myeloma, or metastatic cancer) as well as those with osteoporotic VCFs were excluded unless data relating to participants with osteoporotic fractures could be extracted separately. This was because there is some evidence that the type and incidence of AEs may differ in vertebral fractures of non-osteoporotic origin (e.g., metastatic, traumatic).

Exclusion Criteria

Systematic reviews were excluded from the review of clinical effectiveness and safety, but were retained for discussion and identification of additional relevant primary research studies. Studies which were considered methodologically unsound were excluded from the review, as were the following publication types:

- Animal models
- Preclinical and biological studies
- Narrative reviews, editorials, and opinions
- Non-randomised studies (except for adverse effects)
- Studies published as meeting abstracts only, which reported insufficient methodological details to allow critical appraisal of study quality

In addition, potentially relevant publications were excluded if they had been superseded by later publications and did not contain any additional useful data: this applied to several conference abstracts.

Study Selection

Retrieved studies were selected for inclusion through a two-stage process according to the above inclusion/exclusion criteria. The references identified by the literature searches were assessed for relevance first by title/abstract, and then by full text, excluding at each step studies which did not satisfy those criteria; abstract-only publications were retained for full-text review. One reviewer examined titles and abstracts for inclusion, and screening was checked by a second reviewer on ten per cent of citations. For studies of clinical effectiveness, the kappa coefficient (range 0 to 1) calculated to measure inter-rater reliability was excellent, at 1.0, indicating no discrepancies.

Number of Source Documents

- 28 articles, related to 9 randomised controlled trials were included in narrative synthesis.
- Nine randomised controlled trials were eligible for inclusion in quantitative synthesis (meta-analysis).

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), the University of Sheffield (see the "Availability of Companion Documents" field).

Methods for Reviewing Clinical Effectiveness and Safety

Data Extraction Strategy

Data were extracted independently by two reviewers using a standardised data extraction form (see Appendix 2 of the Assessment Report); discrepancies were resolved by discussion and did not require input from a third reviewer. Where multiple publications relating to the same study were identified, data were extracted and reported as a single study.

Data obtained from the submissions made by the manufacturers have been appraised and commented on where deemed relevant.

Critical Appraisal Strategy

The methodological quality of each study which met the inclusion criteria for the review of clinical effectiveness was assessed independently by two reviewers, and any discrepancies were resolved by discussion. Where a study was reported in more than one publication, its quality was assessed on the basis of the combined data from all relevant publications.

It was stated in the protocol that quality would be assessed according to criteria based on those proposed by Ploeg et al.[1] for the assessment of studies of percutaneous vertebroplasty (see Appendix 3 of the Assessment Report). These criteria were initially adopted because they could be applied to both randomised and non-randomised studies. However, in the event, because sufficient RCTs were identified, it was not necessary to include non-randomised studies, and it was found that the criteria proposed by Ploeg et al.[1] did not discriminate sufficiently between the included RCTs. A new set of criteria was therefore developed: this was based on the criteria proposed by the Center for Reviews and Dissemination (CRD) and the Cochrane Collaboration for assessing the risk of bias in randomised trials, but also incorporated criteria proposed by Ploeg et al.[1] and Furlan et al.[2] which had particular relevance to the interventions under review. These criteria relate to internal validity, and also to external validity, and precision (for details, see Appendix 4 of the Assessment Report). The criterion relating to the blinding of care providers was excluded as such blinding was not possible given the nature of the interventions under review.

The revised quality assessment tool included some questions which led to subsidiary questions to which the answer could be "not applicable". These subsidiary questions have not been included in the risk of bias tables presented in Section 5.2.2 of the Assessment Report.

Methods of Data Synthesis

Due to the potential impact of baseline imbalances in the degree of pain and disability reported by patients with osteoporotic VCFs, it is crucial that outcomes which are reported as continuous data (e.g., pain, disability, and health-related quality of life) are assessed in terms of the difference between the mean changes from baseline in the intervention and control groups, and not in terms of the differences between mean scores at any given point in time. Where the original study investigators presented relevant measures of effect in terms of mean changes from baseline, these have

been included in the data tables not least because in some cases they also adjusted for stratification variables (e.g., treatment centre). Where adjusted data were not reported, mean between-group differences in change from baseline for continuous outcomes were calculated adjusting for the variance of the within treatment change from baseline, where this was made possible by the data. This method generated confidence intervals but not probability (p) values. For dichotomous outcomes, relative risks, with confidence intervals and p values, were calculated using the Cochrane Collaboration Review Manager© Software (version 5.1) if such data were not reported by the study investigators.

Studies which met the review's entry criteria were eligible for inclusion in meta-analyses to estimate summary measures of effect if such meta-analysis was appropriate (i.e., if the study populations, intervention, and outcomes were comparable). Meta-analysis was carried out using random effects models, using Review Manager© Software (version 5.1). Heterogeneity in the meta-analyses was explored through consideration of the study populations, methods, and interventions, by visualisation of results and, in statistical terms, by the χ^2 test for homogeneity and the I^2 statistic. However, such meta-analysis was limited to dichotomous outcomes.

The review team did not undertake meta-analyses of data relating to continuous or quasi-continuous outcomes. Such meta-analysis was considered inappropriate because of the existence of a published meta-analysis of data from the only two double-blind studies of vertebral augmentation. As this meta-analysis used individual patient data, it was of a higher quality than could be achieved using published data. There was considered to be too much heterogeneity to justify combining data from all the studies of PVP in a meta-analysis together with published data from the existing meta-analysis studies.

Cost-Effectiveness

Systematic Review of Existing Cost-Effectiveness Evidence

Previously Published Economic Models of Percutaneous Vertebroplasty (PVP) and Balloon Kyphoplasty (BKP)

From the literature review, only one mathematical model assessing the cost-effectiveness of BKP or PVP in the defined population was found. This concurred with the conclusions presented by the model submitted by Medtronic.

The Models Submitted by the Manufacturers

The Johnson and Johnson Model

Johnson and Johnson submitted a *de novo* cost-effectiveness model to determine the cost-effectiveness of PVP, BKP, operative placebo with local anaesthesia (OPLA) (denoted as 'invasive control procedure' and also as 'sham'), and optimal pain management (termed 'non-invasive management'). The perspective of the analysis was that of direct National Health Service (NHS) and personal and social services costs. In the base case the time horizon was that of one year, with discounting of both costs and benefits at 3.5% per annum in sensitivity analyses extending beyond a one-year time horizon.

The Medtronic Model

Medtronic submitted a Markov tunnel model adapted from the Strom model to determine the cost- effectiveness of kyphoplasty, vertebroplasty, and optimal pain management in patients hospitalised with vertebral compression fractures.

The tunnel approach allows the time in a health state to be reflected in model parameters such as transition probabilities, costs and utilities.

The Assessment Group Model: The Conceptual Model

The conceptual model was constructed to account for two main factors. Firstly the potential difference in EuroQol- 5 dimensions scale (EQ-5D) (mapped from visual analogue scale [VAS] or taken directly from the trial) within the short term due to the intervention and secondly the need to model differential mortality rates which are dependent on the intervention. As there were potentially different mortality rates it was deemed prudent to also model expensive events related to the osteoporotic VCF to take into consideration the fact that patients who live longer may have other disease related events. Thus, the risks of subsequent hip and vertebral fractures were also modelled.

See Section 6 of the Assessment Report and Section 4.2 of the original guideline document for additional information on cost-effectiveness methodology.

[1]Ploeg, W.T., Veldhuizen, A.G., The, B., Sietsma, M.S. Percutaneous vertebroplasty as a treatment for osteoporotic vertebral compression fractures: a systematic review. European Spine Journal 2006; 15(12):1749-1758.

[2]Furlan, A.D., Pennick, V., Bombardier, C., van Tulder, M. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine 2009; 34(18):1929-1941.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients, and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

Medtronic submitted a Markov tunnel model adapted from the Strom model to determine the cost- effectiveness of kyphoplasty, vertebroplasty, and optimal pain management in patients hospitalised with vertebral compression fractures.

Johnson and Johnson developed a 1-year treatment-state model aiming to determine the cost-effectiveness of vertebroplasty, kyphoplasty, optimal pain management, and operative placebo with local anaesthesia using a scenario analysis.

The Assessment Group's model was designed to determine the cost-effectiveness of vertebroplasty, kyphoplasty, optimal pain management, and operative placebo with local anaesthesia.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Assessment Group presented 6 scenarios rather than a base case. Given the uncertainty around whether vertebroplasty or kyphoplasty prolonged life, it organised results into 3 categories based on whether:

- Kyphoplasty prolongs life more than vertebroplasty, which prolongs life more than optimal pain management
- Vertebroplasty and kyphoplasty prolong life more than optimal pain management and
- Vertebroplasty and kyphoplasty do not prolong life more than optimal pain management

The Assessment Group presented results that differed based on whether it took EuroQol- 5 dimensions scale (EQ-5D) directly from the trials or mapped stable visual analogue scale (VAS) scores to EQ-5D. The Committee considered the scenario in which kyphoplasty was assumed to prolong life more than vertebroplasty, while also considering the scenario in which kyphoplasty and vertebroplasty prolong life equally, using EQ-5D data included directly from trials and assuming a later convergence of pain scores.

The Assessment Group had calculated the cost of vertebroplasty in the model assuming that low-viscosity cements would be used in most procedures; this significantly reduced the cost of 85% of procedures in the model. Although high-viscosity cements are being used increasingly in clinical practice because of concerns around cement leakage with low-viscosity cements, the Committee considered it unlikely that high-viscosity cements would be used in most vertebroplasty procedures. The Committee therefore based its recommendation on the Assessment Group's assumption that clinicians would use low-viscosity cement in most procedures.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values

The Committee concluded that including EQ-5D data directly from the trials was appropriate.

Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee identified no health-related benefits that were excluded from the economic model.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost-Effective?

See section on subgroups under Evidence and Interpretation in the original guideline document.

What Are the Key Drivers of Cost-Effectiveness?

Assumptions about mortality benefits associated with vertebroplasty and kyphoplasty.

Most Likely Cost-Effectiveness Estimate (Given as an Incremental Cost-Effectiveness Ratio [ICER])

The Committee acknowledged that the results were extremely sensitive to the mortality benefit assumptions. The Committee concluded that the ICERs established for both kyphoplasty and vertebroplasty were generally at the lower end of what is usually considered to be cost-effective.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups

were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence and a review of this evidence by the Assessment Group. For clinical effectiveness, randomised controlled trials were the main source of evidence. For cost-effectiveness, the manufacturers' and the Assessment Group's economic models were considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures

Potential Harms

For both vertebroplasty and kyphoplasty, adverse reactions can be caused by: needle insertion (such as local or systemic infection, bleeding, and damage to neural or other structures); leakage of bone cement; displacement of bone marrow and other material by the cement; systemic reactions to the cement (such as hypotension and death); and complications related to anaesthesia and patient positioning (such as additional fractures of a rib or the sternum). In addition, there is a small risk that the balloon can rupture in kyphoplasty, which can result in the retention of balloon fragments within the vertebral body.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has osteoporotic vertebral compression fractures and the doctor responsible for their care thinks that percutaneous vertebroplasty, or percutaneous balloon kyphoplasty without stenting, is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed a tool to help organisations put this guidance into practice (listed below). This tool is available on the NICE Web site .
    - A costing statement explaining the resource impact of this guidance

Implementation Tools

Clinical Algorithm

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 55 p. (Technology appraisal guidance; no. 279).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 April

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Dr Amanda Adler (*Chair*), Consultant Physician, Addenbrooke's Hospital; Professor Keith Abrams, Professor of Medical Statistics, University of Leicester; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Professor John Cairns, Professor of Health Economics Public Health and Policy, London School of Hygiene and Tropical Medicine; Professor Fergus Gleeson, Consultant Radiologist, Churchill Hospital, Oxford; Professor Jonathan Grigg, Professor of Paediatric Respiratory and Environmental Medicine, Barts and the London School of Medicine and Dentistry, Queen Mary University London; Professor Daniel Hochhauser, Consultant in Medical Oncology; Dr Neil Iosson, General Practitioner; Anne Joshua, Associate Director of Pharmacy, NHS Direct; Terence Lewis, Lay Member; Dr Rubin Minhas, General Practitioner and Clinical Director, BMJ Evidence Centre; Dr Peter Norrie, Principal Lecturer in Nursing, DeMontfort University; Professor Stephen Palmer, Professor of Health Economics, Centre for Health Economics, University of York; Dr Sanjeev Patel, Consultant Physician and Senior Lecturer in Rheumatology, St Helier University Hospital; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Danielle Preedy, Lay Member; Dr John Rodriguez, Assistant Director of Public Health, NHS Eastern and Coastal Kent; Alun Roebuck, Consultant Nurse in Critical and Acute Care, United Lincolnshire NHS Trust; Roderick Smith, Finance Director, West Kent Primary Care Trust; Cliff Snelling, Lay Member; Marta Soares, Research Fellow, Centre for Health Economics, University of York; Professor Andrew Stevens, Professor of Public Health, Department of Public Health and Epidemiology, University of Birmingham; David Thomson, Lay Member; Dr Nerys Woolacott Senior Research Fellow, Centre for Health Economics, University of York

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 5 p. (Technology appraisal 279). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

- Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis. Technology assessment report. School of Health and Related Research (ScHARR), the University of Sheffield; 2012 Aug. 416 p. Electronic copies: Available from the NICE Web site .
- Osteoporosis overview. NICE pathway. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. (Technology appraisal; no. 279). Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Vertebroplasty and kyphoplasty for spinal compression fractures caused by osteoporosis. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 6p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on June 17, 2013.

The National Institute for Health and Care Excellence (NICE) has granted the National Guideline Clearinghouse (NGC) permission to include summaries of their Technology Appraisal guidance with the intention of disseminating and facilitating the implementation of that guidance. NICE has not verified this content to confirm that it accurately reflects the original NICE guidance and therefore no guarantees are given by NICE in this regard. All NICE technology appraisal guidance is prepared in relation to the National Health Service in England and Wales. NICE has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk .

Copyright Statement

Disclaimer

NGC Disclaimer